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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,345	03/18/2004	Rae Ellen Syverson	KCC 4749.2 (K-C 16,858.2)	5820
321	7590	11/28/2005	EXAMINER	
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,345

Applicant(s)

SYVERSON ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 2-10, 12, 13, 21 and 34-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 14-20 and 22-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8-18-05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of IDS dated 8-18-05 and remarks dated 9-7-05 is acknowledged.

Claims 1-68 are pending. Examiner notes that in response to the election requirement, applicants elected ether as sub-species and stated that claims 1-20 and 22-46 read on the elected sub-species. However, a careful review of the claims shows that only claims 1-20 and 22-33 read on the sub-species, ether and claims 34-68 include the other sub-species. However, the previous action included examination of all the sub-species and not just the elected sub-species, ether. Therefore, the requirement of a sub-species election is no longer present. Accordingly, claims 1, 11, 14-20 and 22-68 are considered for pending claims 2-10, 12, 13 and 21 are withdrawn from consideration as being non-elected.

Response to Arguments

Applicant's arguments, filed 9-7-05 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as follows:

Claim Rejections - 35 USC § 103

1. Claims 1, 11, 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 1204777 in view of D'Augustine.

DE teaches synergistic increase of the bactericidal potency of hexachlorophene by the addition of benzoic acid, aniline or benzamide. In particular, DE teaches that benzamide (reads on instant claimed species) increased the germicidal activity against

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Staphylococcus aureus. DE does not teach the use of benzamide with the claimed articles.

D'Augustine teaches a method for treating intravaginal or transvaginal bacterial, fungal, viral or parasitic infections comprising a device that contains a pharmaceutically effective amount of an antimicrobial, antifungal, antiviral or antiparasitic agent.

D'Augustine teaches the device in the form of a non-absorbent tampon or tampon-like device, intravaginal sponge or ring etc (col. 2, summary of invention, col. 3 & col. 7, lines 1-29, brief description of figure 15). D'Augustine teaches addition of a number of antimicrobial compounds depending on the infection to be controlled in and around vagina. D'Augustine does not teach the claimed compound.

Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the *staphylococcus* inhibiting benzamide of DE on the intra or transvaginal articles such as tampons or vaginal sponge etc., of D'Augustine, in appropriate amounts to inhibit the *S. aureus* infections in and around the vagina because D'Augustine suggests that the delivery of the desired drugs to the vaginal mucosa and vaginal epithelium is effective with the local application of the antimicrobial drugs present on the articles than when administered systemically. Further, optimizing the amount of benzamide on the article, depending on the article (tampon, sponge, ring etc.) so as to achieve the antimicrobial effect with a minimum amount of the antimicrobial.

2. Claims 1, 11, 14-20 and 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,612,045 to Syverson et al ('045) in view of DE 1204777 (DE).

'045 teach articles such as tampons comprising an effective amount of an ether compound in an amount sufficient for inhibiting the production exoprotein by Gram-positive bacteria (claim 1, Table I). The ether compounds of '045 are the same as that claimed in the instant invention (claims and specification). '045 suggest combining other pharmaceutical adjuncts such as anti-inflammatories, antibacterial compounds etc., with the ether compounds, but fails to teach the claimed benzamide.

DE teaches synergistic increase of the bactericidal potency of hexachlorophene by the addition of benzoic acid, aniline or benzamide. In particular, DE teaches that benzamide (reads on instant claimed species) increased the germicidal activity against *Staphylococcus aureus*. DE does not teach the use of benzamide with the claimed articles.

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine the benzamide of DE with the toxin inhibiting ether compounds of '549 and apply to the articles such as feminine napkins or tampons because '549 teach feminine hygiene products coated with antimicrobial agents such as ether for the inhibition of exoprotein (toxin) by Gram positive bacteria and DE also teaches benzamide for *S. aureus* inhibition, constituting analogous art. Accordingly, a skilled artisan would have expected a synergistic increase inhibition of exoprotein production by benzamide and ether compounds. Further, optimizing the amounts of amounts of benzamide on the articles of '549 so as to achieve the desires antimicrobial

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effect would have been within the scope of a skilled artisan. While the Syverson does not specifically state non-absorbent articles, absent any unexpected results with respect to the non-absorbency of the articles, it would have been within the scope of a skilled artisan to use either a non-absorbent or absorbent article for incorporating the above antimicrobial compounds and still achieve the same effect.

3. Claims 1, 11, 14-20 and 48-55 are rejected as being unpatentable over US 5,685,872 ('872) to Syverson in view of DE 1204777.

'872 teach articles such as a tampon or feminine hygiene pad comprising an effective amount of active agents such as disodium lauramphodiacetate, lauramide monoethanolamine etc., for inhibiting the exoprotein production by Gram-positive bacteria (see abstract and table II). '872 fail to teach benzamide.

DE teaches synergistic increase of the bactericidal potency of hexachlorophene by the addition of benzoic acid, aniline or benzamide. In particular, DE teaches that benzamide (reads on instant claimed species) increased the germicidal activity against *Staphylococcus aureus*. DE does not teach the use of benzamide with the claimed articles.

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine the benzamide of DE with the toxin inhibiting ether compounds of '872 and apply to the articles such as feminine napkins or tampons because '872 teach feminine hygiene products coated with antimicrobial agents such as ether for the inhibition of exoprotein (toxin) by Gram positive bacteria and DE also

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teaches benzamide for *S. aureus* inhibition, constituting analogous art. Accordingly, a skilled artisan would have expected a synergistic increase inhibition of exoprotein production by benzamide and ether compounds. Further, optimizing the amounts of amounts of benzamide on the articles of '872 so as to achieve the desired antimicrobial effect would have been within the scope of a skilled artisan. While the Syverson does not specifically state non-absorbent articles, absent any unexpected results with respect to the non-absorbency of the articles, it would have been within the scope of a skilled artisan to use either a non-absorbent or absorbent article for incorporating the above antimicrobial compounds and still achieve the same effect.

4. Claims 56-62 are rejected as being unpatentable over US 5,618,554 to Syverson ('554) in view of DE 1204777.

'554 teaches articles such as a tampon or feminine hygiene pad comprising an effective amount of active agents such as disodium lauramphodiacetate, lauramide monoethanolamine etc., for inhibiting the exoprotein production by Gram-positive bacteria (see abstract and table II).

DE teaches synergistic increase of the bactericidal potency of hexachlorophene by the addition of benzoic acid, aniline or benzamide. In particular, DE teaches that benzamide (reads on instant claimed species) increased the germicidal activity against *Staphylococcus aureus*. DE does not teach the use of benzamide with the claimed articles.

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine the benzamide of DE with the toxin inhibiting ether compounds of '554 and apply to the articles such as feminine napkins or tampons because '554 teach feminine hygiene products coated with antimicrobial agents such as ether for the inhibition of exoprotein (toxin) by Gram positive bacteria and DE also teaches benzamide for *S. aureus* inhibition, constituting analogous art. Accordingly, a skilled artisan would have expected a synergistic increase inhibition of exoprotein production by benzamide and ether compounds. Further, optimizing the amounts of amounts of benzamide on the articles of '554 so as to achieve the desired antimicrobial effect would have been within the scope of a skilled artisan. While the Syverson does not specifically state non-absorbent articles, absent any unexpected results with respect to the non-absorbency of the articles, it would have been within the scope of a skilled artisan to use either a non-absorbent or absorbent article for incorporating the above antimicrobial compounds and still achieve the same effect.

Allowable Subject Matter


Claims 32-47 and 63-68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
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November 23, 2005